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APPLICATION NO. FIRST NAMED INVENTOR FILING DATE ATTORNEY DOCKET NO. CONFIRMATION NO. 09/808,228 03/14/2001 10557/199332 Brian W. McKinnon 5554

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CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116

EXAMINER BARRETT, THOMAS C

ART UNIT PAPER NUMBER

3738 DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)		
Office Action Summary		09/808,228	MCKINNON, BRIAN W.		
		Examiner	Art Unit		
		Thomas C. Barrett	3738		
Period fo	The MAILING DATE of this communication ap r Reply	pears on the cover sheet with the c	correspondence address		
THE N - Exter after - If the - If NO - Failur - Any n	DRTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. sions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a rep period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statutely received by the Office later than three months after the mailing d patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tired by within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	nely filed  s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).		
1)⊠	Responsive to communication(s) filed on <u>02</u>	<u>April 2003</u> .			
2a) 🗌	This action is <b>FINAL</b> . 2b)⊠ T	his action is non-final.			
3)□ Dispositi	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. sition of Claims				
-	Claim(s) <u>1-181</u> is/are pending in the application	ion			
-	4a) Of the above claim(s) <u>1-101,111-115,131-</u>		31 is/are withdrawn from		
considera		, , , , , , , , , , , , , , , , , , , ,	_		
	Claim(s) is/are allowed.				
•	Claim(s) 102-110,116-130,135,138,139 and	143 is/are rejected.			
,	Claim(s) is/are objected to.	-			
•	Claim(s) are subject to restriction and/	or election requirement.			
•	ion Papers				
9)🖾	The specification is objected to by the Examin	er.			
10)	The drawing(s) filed on is/are: a)□ acc	epted or b) objected to by the Exa	aminer.		
	Applicant may not request that any objection to t				
11) 🗌	The proposed drawing correction filed on	is: a)□ approved b)□ disappr	oved by the Examiner.		
	If approved, corrected drawings are required in r				
	The oath or declaration is objected to by the E	xaminer.			
_	under 35 U.S.C. §§ 119 and 120				
, —	Acknowledgment is made of a claim for foreign	gn priority under 35 U.S.C. § 119(	a)-(d) or (f).		
a)	☐ All b)☐ Some * c)☐ None of:				
	1. Certified copies of the priority documen				
	2. Certified copies of the priority document				
* (	3. Copies of the certified copies of the pri application from the International E See the attached detailed Office action for a list	Bureau (PCT Rule 17.2(a)).			
14)🛛	Acknowledgment is made of a claim for domes	stic priority under 35 U.S.C. § 119	(e) (to a provisional application).		
	a)  The translation of the foreign language p Acknowledgment is made of a claim for dome				

Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Re 3) Information Disclosure Statement(s) (PTO-1)		Interview Summary (PTO-413) Paper No(s) Notice of Informal Patent Application (PTO-152) Other:
U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)	Office Action Summary	Part of Paper No. 10

#### **DETAILED ACTION**

#### Election/Restrictions

Claims 1-101, 111-115, 131-134, 136-137, 140-142, and 144-181 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Applicant's election with traverse of Species I, sub-species (i), and sub-sub-species (A) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that a different field of search is not required for examination. This is not found persuasive because in a restriction of species that are independent inventions, it is not necessary to show a separate status in the art or separate classification. Therefore a species restriction does not require further search or significant burden.

Furthermore, as noted in the prior action: "Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case."

The requirement is still deemed proper and is therefore made FINAL.

#### Information Disclosure Statement

The information disclosure statement filed August 27, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Harkness, et al. reference does not have a date and place of publication. The Harkness et al. reference

has not been considered as to the merits. Applicant is advised that the date of any resubmission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

## Specification

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The use of the trademarks "UNIGRAPHICS", "WINDOWS NT", PENTIUM II" and "SYNERGY" has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the liner internal concave surface is only disclosed as shifted laterally up to 8 mm or medially up to 4 mm. Additionally, the center axis of the liner internal concave surface is only disclosed as anteverted 20 degrees.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 107-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 107-108 are ambiguous and therefore indefinite as to whether the Applicant is claiming a product ("femoral component" or a process ("employing femoral components to define said sculpted surface").

### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 107-110 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 107-110 are directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only.

Please Note: The products of the prior art cited below have the same **structural** limitations as those claimed.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 102-106, 135, 138-139 and 143 are rejected under 35 U.S.C. 102(b) as anticipated by Thornberry et al. as disclosed in applicant's IDS. Thornberry et al. disclose a prosthetic device comprising: an acetabular shell, an acetabular liner and a femoral component. (See "Results and Discussion"). The shape of the sculpted surface varies around the rim of the liner ("wide chamfer") and is symmetric about a plane ("small chamfer").

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Claims 102 and 117-124 are rejected under 35 U.S.C. 102(b) as anticipated by Smith & Nephew (Reflection Lateralized Liners...) as disclosed in applicants IDS. Smith & Nephew discloses a prosthetic device comprising: an acetabular shell and an acetabular liner. The liner has a distance across the opening of the internal concave surface of 28mm, a shoulder, a serrated locking surface and a lateral offset of 4mm. The external surface of the "Lateralized Liners" is adapted to be received in a "Reflection InterFit" acetabular shell, which, as disclosed in the "Catalog Information" of "Smith & Nephew Surgical Technique" as cited in applicant's IDS, has an external diameter of 42-76 mm.

Claims 102 and 126-130 are rejected under 35 U.S.C. 102(b) as anticipated by Lennox. Lennox discloses a prosthetic device comprising: an acetabular shell and an acetabular liner (Fig. 1). The liner has a center axis oriented 20 degrees to the axis of the shell (col. 8, lines 51-64).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 102, 122 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. Bateman et al. discloses a prosthetic device comprising: an acetabular shell, an acetabular liner and medially shifted liner (Fig. 4)

however Bateman et al. fails to disclose the liner shifted medially specifically up to 8 mm.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to shift the liner medially specifically up to 8 mm. Applicant has not disclosed that shifting the liner medially specifically up to 8 mm provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the liner medially shifted specifically up to 8 mm because there is no disclosed advantage over a specific length of medial shift.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Bateman et al. to obtain the invention as specified in claim 125.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3580 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0850.

Thomas Barrett June 20, 2003

CORRINE McDERMOTT SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700